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TITLE: A Randomized, Crossover Clinical Trial of Exoskeletal-Assisted Walking to Improve Mobility, Bowel Function, and Cardiometabolic Profiles in Persons with SCI

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14. ABSTRACT
The primary objective is to achieve specific walking velocities and distances using a powered exoskeletal over the course of 36 sessions in 3 months in people with chronic SCI who are wheelchair users for community mobility. The secondary objectives are to determine if this amount of exoskeletal-assisted walking is effective in improving bowel function and body composition. Exploratory objectives include questions concerning the retention or non-retention of the positive changes, effects of increased physical activity on vagal tone, orthostatic tolerance, lipid profile, total testosterone, estradiol levels, and quality of life. During this research period (year 2), 42 participants were consented for Screening; 14 of which were screen failures. The Screening failure reasons included: low bone mineral density (6), schedule conflicts (4), contractures (2), SCI level exclusion (1), and severe spasticity (1). The remaining 28 participants were randomized. The first 10 participants to complete both arms of the study were analyzed for preliminary data for the primary outcome variables. In these first 10 participants, 60% were able to walk ≥0.25 m/s at 12 sessions and 70% achieved this velocity at 36 sessions. Of note, 30% of the participants achieved a velocity of ≥0.40 m/s [the FDA requirement for personal prescription].

15. SUBJECT TERMS
Exoskeletal Assisted Walking (EAW), Mobility, Bowel Function, Cardiometabolic profile

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1. INTRODUCTION:

The primary objectives of this proposal are to achieve successful walking skills in the exoskeletal-assisted walking devices for an extended period of time and at specific velocities and distances over the course of 36 sessions in three months in people with chronic SCI who are wheelchair users for community mobility. The secondary objectives are to determine if 36 sessions in three months of walking is effective in improving bowel function and body composition. The exploratory objectives are to address additional questions concerning the retention or non-retention of positive changes, the effects of the increased physical activity from exoskeletal-assisted walking on vagal tone, orthostatic tolerance, lipid profile, total testosterone, estradiol levels, and quality of life (QOL).

2. KEYWORDS:

Powered exoskeletons, paraplegia, tetraplegia, high density lipoprotein, lipid profile, orthostatic tolerance, total testosterone, estradiol, quality of life, ReWalk, and Ekso

3. ACCOMPLISHMENTS:

In Year 1 (10/01/2014 to 09/30/2015) we had a 6-month delay with the start-up activities (regulatory approvals). This delayed the first participant enrollment/randomization by six months. However, we are catching up and will soon be on target for enrollment. As of 01-Oct-2016, we have completed Major Task 1, Subtask 1-3. We have completed Major Task 2, Subtask 1 & 2 at 100% and Subtask 3 at 70%.

What were the major goals of the project?
The Major Tasks and Subtasks for the first two years of the study are reported by task, timeline, percent of task completed and date of completion (Table 1).

Table 1. Statement of Work	**Timeline (Months)**	**% Completed**	**Date Completed**
Major Task 1: Study start-up and continuation administrative functions			
Subtask 1: Prepare Regulatory Documents and Research Protocol			
If Applicable, coordinate with Sites for CRADA* submission	n/a		
If Applicable, coordinate with Sites for material transfer agreements (MTAs) or clinical trial agreements (CTAs) submission	n/a		
If Applicable, coordinate with Sites for nondisclosure agreements (NDAs)	n/a		
If applicable, indicate time required for submission and exemption of an Investigational Device Exemption (IDE) application to the U.S. Food and Drug Administration	n/a		

		Refine eligibility criteria, exclusion criteria, screening protocol	1-3	100%	30-Dec-14
		Finalize consent form & human subjects protocol	1-3	100%	30-Dec-14
		Coordinate with Sites for Local IRBs** protocol submission	1-3	100%	30-Dec-14
		Coordinate with Sites for University IRB** review	1-6	100%	30-Dec-14
		Coordinate with Sites for Military 2nd level IRB** review (ORP/HRPO)	1-6	100%	30-Dec-14
		Submit amendments, adverse events and protocol deviations as needed	As needed		Ongoing
		Coordinate with Sites for annual IRB** report for continuing review	Annually	100%	Ongoing
		Milestone Achieved: Local IRB** approval at BVMRF, UMROI, and KFRC	3	100%	30-Mar-15
		Milestone Achieved: HRPO*** approval for all protocols and local IRB** approvals.	6	100%	30-Mar-15
	Subtask 2: Coordinate with Sites for job descriptions design		1-3	100%	30-Dec-14
		Advertise and interview for project related staff	1-3	100%	30-Dec-14
		Coordinate for space allocation for new staff	1-3	100%	30-Dec-14
		Coordinate with Sites for hiring and training of staff	1-6	100%	30-Dec-14
		Coordinate with Sites for providing standard training procedures among exoskeletal-trainers	1-6	100%	9-Apr-15
		Milestone Achieved: Research staff hired and begin staff training	6	100%	30-Dec-14
	Subtask 3: Facilitate and Coordinate with Sites for hiring, training, supervision and fidelity checks as needed for study participant attrition		6-48	100%	30-Dec-14
		Coordinate multi-site training meeting for exoskeletal training, walking assessments standardization, data collection: case report forms and web-based forms, and use of log record	3-6	100%	9-Apr-15
		PI, Lead Engineer and Study Coordinator travel to Sites for staff training of procedures	3-6	100%	9-Apr-15
		Coordinate multi-site training meeting for standardization of SCI QOL and bowel function assessments	3-6	100%	9-Apr-15
		Coordinate multi-site training meeting for blood draw procedures	3-6	100%	9-Apr-15
		Coordinate multi-site training meeting for orthostatic tolerance test and Holter monitor assessment	3-6	100%	9-Apr-15
		Coordinate with Sites for training to maintain 100% concordance with Study protocol	6-48	100%	9-Apr-15
		Milestone Achieved: Maintained trained Study staff throughout duration of the clinical trial	6-48	100%	9-Apr-15
Major Task 2: Study recruitment and enrollment					

	Subtask 1: Begin participant screening and consenting process	6-7	100%	11-May-15
	Milestone Achieved: Participant #1 consented, randomized and enrolled at each Site	6-7	100%	14-Aug-15
	Subtask 2: Randomize the first 4 participants at each respective Site	7-15	100%	22-Sep-15
	Complete participant baseline evaluations	7-15	100%	10-Oct-15
	Complete participant weekly and monthly evaluations	7-15	100%	1-Apr-16
	Complete participant post evaluations	7-15	100%	1-Apr-16
	Milestone Achieved: 12 participants consented, screened, randomized, and enrolled for the study	7-15	100%	22-Sep-15
	Subtask 3: Randomize the next 8/6/4 participants at each respective Site	16-24	70%	1-Oct-16
	Complete participant baseline evaluations	16-24	70%	1-Oct-16
	Complete participant weekly and monthly evaluations	16-24	70%	1-Oct-16
	Complete participant post evaluations	16-24	70%	1-Oct-16
	Milestone Achieved: 30 participants consented, screened, randomized, and enrolled for the study	16-24	70%	1-Oct-16

What was accomplished under these goals?

We have successfully randomized 28 of the 30 targeted participants to date. The database is running well and data from the sites is routinely uploaded. We anticipate analyzing some of the preliminary data on at least 10 participants in late November, 2016. This data will be used to submit one to three abstracts to the Academy of Spinal Cord Injury Professionals (ASCIP). The due date for the ASCIP meeting is in January 2017.

Methods

A Phase III randomized clinical trial (RCT) is being performed using a crossover design and employing an exoskeletal-assisted walking intervention and a usual activities (UA) arm, as the control, in 64 persons with chronic SCI (>6 month post injury) who are wheelchair-dependent for outdoor mobility in the community. Eligible participants are being randomized (within site) to one of two groups for 12 weeks (three months): Group 1 (n=32) are receiving exoskeletal-assisted walking (WALK) first for 12 weeks then crossover to UA for a second 12 weeks; Group 2 (n=32) receives UA first for 12 weeks then cross-over to the WALK arm for 12 weeks of training. The WALK arm consists of supervised exoskeletal-assisted walking training, three sessions per week (4-6 h/week) for 36 sessions for the second 12-week period. The UA arm consists of identification of usual activities for each participant, encouragement to continue with these activities and attention by study team members throughout the 12-week UA arm. The UA are recorded in a weekly log. A fixed answer format is used to capture this information.
This study is being conducted at three sites: JJPVAMC, Kessler Foundation and UMROI. Site details are provided in Section 7. All sites have received Institutional Board approval for the study of human subjects and all participants were provided details and risks about the study, permitted ample time to ask questions and provide informed consent prior to screening.

Baseline screening evaluations for eligibility included a history and physical examination with a complete International Standards for Neurological Classification of SCI (ISNCSCI) examination [the ISNCSCI includes a full American Spinal Cord Injury Impairment Scale (AIS)], range of motion, Ashworth spasticity examination at selected lower extremity joints, a standard orthostatic tolerance test, and bone mineral density (BMD) evaluations. Participants were screened for safety and medical eligibility as stated in the protocol inclusion and exclusion criteria.

The total number of participants screened and enrolled and the incidence and reasons for screening failures is reported (Table 2). The numbers reported reflect enrollment data as of October 01, 2016.

Table 2. Enrollment	**JJPVAMC**	**UMROI**	**Kessler**	**Total**
Number screen consented	**24**	**11**	**8**	**43**
Screen failure reasons:	**11**	**3**	**0**	**14**
Low BMD	5	1	0	6
Schedule conflict/no time	3	1	0	4
Injury level outside criteria	0	1	0	1
Ankle/Foot Contractures	2	0	0	2
Severe Spasticity	1	0	0	1
Number randomized	**12**	**8**	**8**	**28**
Number completed	5	2	3	10
Number withdrawn[1]	1	2	1	4
Number currently enrolled	7	4	4	15
Net total completed or enrolled	**11**	**4**	**6**	**21**
Completed # projected in SOW	12	10	8	30
Percent of Target [2]	**0.92**	**0.40**	**0.75**	**0.70**
Enrollment plan for next 2 years				
01-Oct-16 to 30-Sep-17	10	8	5	23
01-Oct-17 to 30-Sep-18	7	8	5	20
Total number targeted for study	**28**	**20**	**16**	**64**

[1] Three were withdrawn for unrelated medical reasons and 1 for pre-existing should injury and was unable to train after 3 sessions.

[2] Enrollment is good, but we were about 6 months delayed in getting started. We are confident that we can make it up over the next two years with the enrollment plan as shown. If we are not able to do so, the Bronx site is prepared for a no cost extension for 6 to 12 months to complete the enrollment goals.

The Primary Aims consist of the following:

1. By session 12 (first month of WALK training), the participants will be able to perform the following exoskeletal-assisted walking tests with or without minimal assistance:
    a. 10m WT
        i. 90% in ≤60 seconds (≥0.17 m/s)
        ii. 10% in ≤40 seconds (≥0.25 m/s)
    b. 6min WT
        i. 80% at a distance of ≥50 m (≥0.14 m/s)
        ii. 20% at a distance ≥80 m (≥0.22 m/s);
    c. TUG
        i. 80% in ≤120 seconds
        ii. 20% in ≤90 seconds

2. By session 36 (three months of WALK training), participants will have improved their ability to walk faster and longer distances and will be able to perform exoskeletal-assisted walking tests with or without minimal assistance as follows:
    a. 10m WT - 70% in ≤40 seconds (≥0.25 m/s)
    b. 6min WT - 70% at a distance ≥80 m (≥0.22 m/s)
    c. TUG - 60% in ≤90 seconds.

The Secondary Aims are to affect the following by three months of exoskeletal-assisted walking (WALK):

1. To improve bowel function as measured by established survey instruments; and
2. To reduce total body fat mass and percent as measured by DXA.

Preliminary descriptive analyses were performed on the first 10 participants to complete the study. No comparative statistics were performed for the pre and post values because of the small sample size. Even though analyses of the data were not scheduled until next year's annual report (as stated in the revised SOW), preliminary data were summarized for the three walking tests and the bowel and bladder surveys. Body composition data will be analyzed in next year's report. More detailed statistical analyses will be performed as per the SOW in future annual reports.

Results

According to the SOW, the initial analyses for preliminary results of the primary, secondary and exploratory outcome data is scheduled to begin in months 24 to 40 (October 1, 2016 to December 30, 2017), after this report. However, in preparation for the Spinal Cord Injury Research Program (SCIRP) In-Progress Review Meeting, October 25-26, 2016 at Fort Detrick, preliminary analyses for first 10 participants who have completed the study was performed for the ten meter walk test (10MWT), six-minute walk test (6MWT), the primary aim for percent who achieve the goals, and the bowel and bladder survey data. A summary, in table format and text description, follows for each of these analyses (Tables 3 to 7).

Table 3. Demographic Characteristics (n=10)							
SID	**GRP**	**Age**	**Gender**	**Ethnicity**	**DOI (y)**	**ASIA**	**LOI**
101	1	24	Male	H	6.0	D	L1
103	1	30	Female	A/PI	0.6	A	T3
105	1	66	Male	W	3.0	A	T2
301	1	60	Male	AI/AN	3.0	D	T11
304	1	30	Male	W	4.0	B	C6
104	2	29	Female	B	3.0	D	T10
106	2	45	Male	W	0.6	A	T4
201	2	38	Male	B	1.5	A	T8
203	2	57	Male	W	10.0	B	T11
303	2	21	Male	B	5.0	A	T3

SID=study ID #; GRP=randomized group; DOI=duration of injury; Y=years; LOI=level of Injury; H=Hispanic; A/PI=Asian Pacific Islander; B=Black; W=white; AI/AN=American Indian/Native American;

The demographic characteristics of the first ten participants to complete the study are reported (Table 3). They ranged in age from 21 to 66 years old and duration of SCI from 0.6 months to 10 years. Eighty percent were males and 90% had paraplegia.

The walking test results for the 10MWT, 6MWT and the TUG are reported (Table 4). Nine of the ten participants were able to complete the 10MWT and 6MWT by the 12th session and only 50% of the participants were able to perform the TUG by the 12th session. Overall, all participants improved their speeds and distances over the course of the 36-session intervention.

Table 4. Walking Tests Results (n=10)										
SID	**GRP**	**10MWT(s)**			**6MWT (m)**			**TUG (s)**		
		Sessions			**Sessions**			**Sessions**		
		12	**24**	**36**	**12**	**24**	**36**	**12**	**24**	**36**
101	1	20	20	22	163	174	161	84	59	55
103	1	32	42	34	103	83	107	123	66	48
105	1	24	22	22	137	154	159	NT	50	41
301	1	77	65	61	44	47	59	91	114	101
304	1	41	27	20	86	131	160	NT	145	66
104	2	34	34	30	84	106	121	NT	82	55
106	2	31	31	30	88	110	133	NT	57	48
201	2	38	64	62	48	66	62	NT	106	101
203	2	38	37	33	84	89	110	84	63	53
303	2	NT	56	50	NT	65	67	NT	90	74

10MWT = time, in seconds, to walk ten meters ; 6MWT = distance in meters walked in 6 minutes; TUG = timed up an go, time to go from sit to stand, walk 10 ft, turn around, walk back the the chair and perform stand to sit. NT = not tested/unable to perform test.

Primary aims 1. a, b, and c (above) were calculated for the percent of participants who achieved the walking speeds or distances described (Table 5). The actual percent of participants who passed are summarized in the % Pass row and the percent from the hypotheses are presented in the SOW row (Table 5). There appears to be a trend for the 10MWT and 6MWT goals to be underestimated and the TUG to be overestimated, however with only ten participants, conclusions cannot be drawn.

The Average of the 10 participants showed that bowel and bladder management trended to improve after the intervention (Table 6).

Table 5. Primary Aim 1: Percent Who Achieved Goals (n=10)										
		Ten m WT			Six Min WT			TUG		
Aim:		≤60 s (0.≥17 m/s)	≤40 s (≥0.25 m/s)		≥50 m (≥0.14 m/s)	≥80 m (≥ 0.22 m/s)		≤120 s	≤90 s	
SID	GRP	Sessions			Sessions			Sessions		
		12	12	36	12	12	36	12	12	36
101	1	1	1	1	1	1	1	1	1	1
103	1	1	1	1	1	1	1	0	0	1
105	1	1	1	1	1	1	1	0	0	1
301	1	0	0	0	0	0	0	1	0	0
304	1	1	0	0	1	1	1	0	0	1
104	2	1	1	1	1	1	1	0	0	1
106	2	1	1	1	1	1	1	0	0	1
201	2	1	1	0	0	0	0	0	0	0
203	2	1	1	1	1	1	1	0	1	1
303	2	0	0	0	0	0	0	1	0	1
% Pass		80%	70%	60%	70%	70%	70%	30%	20%	80%
SOW		90%	10%	70%	80%	20%	70%	80%	20%	60%

1 = Pass; 0 = Fail

Note: FDA Advanced skills test for personnal use Rx include 10MWT ≥0.40 m/s (≤25s): 3 of 10 would have passed by 36 sessions.

Table 6. Bowel and Bladder Changes after WALK Arm (n=10)							
SID	Grp	Bowel Management			Bladder Management		
		Pre	Mid	Pos	Pre	Mid	Pos
101	1	48.5	41.9	36.1	43.7	37.4	46.6
103	1	54.5	50.5	56.5	68.5	62.9	63.8
105	1	59.8	59.0	59.0	54.2	58.5	55.0
301	1	59.5	60.9	63.2	59.0	55.0	56.2
304	1	52.7	51.0	46.8	55.0	56.8	53.5
104	2	48.5	36.1	43.6	67.0	69.9	63.8
106	2	43.6	44.3	41.9	53.5	49.6	49.6
201	2	44.3	40.7	40.7	59.0	52.6	54.2
203	2	57.3	52.3	47.8	59.0	51.7	46.6
303	2	47.8	48.5	36.1	46.6	49.6	42.0
Mean		51.7	48.5	47.2	56.6	54.4	53.1
SD		6.0	7.9	9.5	7.8	8.7	7.2

Bowel and bladder management scores represent values from those item banks from the SCI QOL. Lower scores represent better scores. There is an average trend for improvement in both scales.

In summary, the recruitment is going well and we are collecting the data as expected. These early preliminary analyses are encouraging, but conclusions cannot be made on 1/6th of the total sample projected to be studied.

What opportunities for training and professional development has the project provided?
Nothing to report

How were the results disseminated to communities of interest?
Some of the preliminary results for walking velocities for the first 10 participants were shared at the Spinal Cord Injury Research Program (SCIRP) In-Progress Review Meeting, October 25-26, 2016 at Fort Detrick.

What do you plan to do during the next reporting period to accomplish the goals?
Enrollment will continue as scheduled. An extra ReWalk unit from the BVMRF will be loaned to UMROI to assist them with scheduling for training of their enrolled participants.

4. IMPACT: Nothing to Report

What was the impact on the development of the principal discipline(s) of the project?
Nothing to Report

What was the impact on other disciplines? Nothing to Report
What was the impact on technology transfer? Nothing to Report
What was the impact on society beyond science and technology? Nothing to Report

5. CHANGES/PROBLEMS: Nothing to Report

Changes in approach and reasons for change: Nothing to Report
Actual or anticipated problems or delays and actions or plans to resolve them: Nothing to Report
Changes that had a significant impact on expenditures: Nothing to Report
Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents: N/A, Nothing to Report
Significant changes in use or care of human subjects: Nothing to Report
Significant changes in use or care of vertebrate animals: N/A, Nothing to Report
Significant changes in use of biohazards and/or select agents: N/A, Nothing to Report

6. PRODUCTS: Nothing to Report

- **Publications, conference papers, and presentations:** Nothing to Report
  Journal publications: Nothing to Report
  Books or other non-periodical, one-time publications: Nothing to Report
  Other publications, conference papers and presentations: Nothing to Report
  Website(s) or other Internet site(s): Nothing to Report

- **Technologies or techniques:** Nothing to Report
- **Inventions, patent applications, and/or licenses:** Nothing to Report
- **Other Products:** Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Bronx Veterans Medical Research Foundation (BVMRF)		**Status**
Name:	**Ann M. Spungen, EdD**	No change
Project Role:	Principal Investigator	
Nearest person month worked	1.20	
Contribution to the Project	Principal Investigator	
Funding Support	JJPVAMC	
Name:	**Pierre K. Asselin, MS**	No change
Project Role:	Co-Investigator	
Nearest person month worked	1.20	
Contribution to the Project	Biomedical Engineer	
Funding Support	VA RR&D Center	
Name:	**Stephen D. Kornfeld, DO**	No change

Project Role:	Co-Investigator	
Nearest person month worked	0.60	
Contribution to the Project	Study physician/ medical examinations	
Funding Support	JJPVAMC SCI Service	
Name:	**Jill M. Wecht, EdD**	No change
Project Role:	Co-Investigator	
Nearest person month worked	0.36	
Contribution to the Project	Autonomic and orthostatic outcomes	
Funding Support	JJPVAMC	
Name:	**William A. Bauman, MD**	No change
Project Role:	Co-Investigator	
Nearest person month worked	0.36	
Contribution to the Project	Endocrine outcomes	
Funding Support	JJPVAMC	
Name:	**Steven Knezevic, MS**	No change
Project Role:	Lead Research Coordinator	
Nearest person month worked	6.00	
Contribution to the Project	Study Coordinator, site primary trainer	
Funding Support	BVMRF and VA RR&D Center	
Name:	**Eun-Kyoung Hong, PhD**	New
Project Role:	Study Database Manager	
Nearest person month worked	9.00	
Contribution to the Project	Database developer/manager, Primary trainer	
Funding Support	BVMRF	
Name:	**Denis Doyle-Green**	No change
Project Role:	Research assistant	
Nearest person month worked	6.00	
Contribution to the Project	Assistant trainer and phlebotomist for study	
Funding Support	BVMRF	
University of Maryland Rehabilitation Orthopedic Institute (UMROI)		**Status**
Name:	**Peter H. Gorman, MD, PhD**	No change
Project Role:	Co-Principal Investigator	
Nearest person month worked	0.60	
Contribution to the Project	Site PI and study physician	
Funding Support	UMROI	
Name:	**Paula R. Geigle, PhD, PT**	No change
Project Role:	Co-Investigator	
Nearest person month worked	0.60	
Contribution to the Project	Physical therapist	
Funding Support	UMROI	
Name:	**William Scott, MA**	No change

Project Role:	Research coordinator	
Nearest person month worked	3.00	
Contribution to the Project	Primary trainer	
Funding Support	UMROI	
Name:	**Rebecca Webb, PT**	New
Project Role:	Site research coordinator	
Nearest person month worked	3.00	
Contribution to the Project	Trainer, physical therapist	
Funding Support	UMROI	
Kessler Foundation Research Center (KF)		**Status**
Name:	**Gail F. Forrest, PhD**	No change
Project Role:	Co-Investigator	
Nearest person month worked	1.20	
Contribution to the Project	Site PI	
Funding Support	KF	
Name:	**Leigh Ann Martinez**	No change
Project Role:	Site research coordinator	
Nearest person month worked	12.00	
Contribution to the Project	Recruitement, IRB administrative paperwork	
Funding Support	KF	
Name:	**Steven C. Kirshblum, MD**	No change
Project Role:	Site physician	
Nearest person month worked	0.36	
Contribution to the Project	Study physician/ medical examinations	
Funding Support	Kessler Institute for Rehabilitation	
Name:	**Jonathan Augustine**	New
Project Role:	Research assistant	
Nearest person month worked	4.00	
Contribution to the Project	Primary trainer	
Funding Support	KF	
Name:	**Erica Garbrini, PT**	No change
Project Role:	Physical therapist	
Nearest person month worked	6.00	
Contribution to the Project	Primary trainer, physical therapist	
Funding Support	KF	
Name:	**Christopher Cirnigliaro, MS**	No change
Project Role:	Study assistant	
Nearest person month worked	2.00	
Contribution to the Project	Body composition assessments	
Funding Support	VA RR&D Center	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
There is nothing to report for theAnn M. Spungen, PI or Peter Gorman, Co-PI.
Gail Forrest, Co-Inv and Site PI for KF reports the following other support changes.

SC140099 (Bloom, PI) 9/30/15 – 9/29/19 0.60 CM (5%)
USAMRAA/CDMRP/DoD
Subrecipient Agreement from Feinstein Institute
"Biomarkers of Spontaneous Recovery from Traumatic Spinal Cord Injury"
$52,669 (Annual Directs)
$236,693 (Total Award)
The major goals of this project are to measure blood levels of some inflammatory biomarkers that correlate inversely with functional recovery throughout the first year after spinal cord injury (SCI).
Role: Co-I
POC for Funding Agency: Ms. Skye Lonsberry, M.S., Science Officer, (301) 619-7068

90RE5021 (Foulds, PI) 9/30/15 – 9/29/21 0.60 CM (5%)
NIDILRR $159,331 (Annual Directs)
Subrecipient Agreement $995,821 (Total Award)
From New Jersey Institute of Technology
This main goal of the study is to evaluate if the combination of interventions of the exoskeleton assisted walking (EAW) with transcutaneous lumbosacral stimulation (TLS) would increase the excitability of the cord and afferent input when training in the exoskeleton to increase lower extremity muscle firing and to functionally increase walking speed
Role: Co-I
POC for Funding Agency: Thomas Corfman, Program Officer, One Massachusetts Ave., Administration for Community Living, Washington, DC 20201-1401, Phone: 202-245-7306

What other organizations were involved as partners? Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

A Randomized, Crossover Clinical Trial of Exoskeletal-assisted Walking to Improve Mobility, Bowel Function and Cardio-Metabolic Profiles in Persons with SCI

Insert ERMS/Log Number and Task Title (Unknown)
SC130234

PI: Dr. Ann M. Spungen **Org:** Bronx Veterans Medical Research Foundation **Award Amount:** $1,555,889

Study/Product Aim(s)

The **primary objectives** are to achieve successful walking skills in the exoskeletal-assisted walking devices for an extended period of time and at specific velocities and distances over the course of 36 sessions in three months in people with chronic SCI who are wheelchair dependent for community mobility. The **secondary objectives** are to determine if this amount of walking is effective in improving bowel function and body composition.

Approach

A two-group, Phase III randomized clinical trial (RCT) is being performed using a crossover design with an exoskeletal-assisted walking intervention. Group 1 serves as the intervention follow-up to assess retention/non-retention of change due to the intervention on the outcome variables. Group 2 will serve as a lead-in to assess stability of the outcome variables prior to the intervention.

Panel A – Participant with motor incomplete paraplegia (T11, AIS D) walking in the ReWalk exoskeleton. Panel B - Participant with motor complete paraplegia (T3, AIS A) walking in the Ekso exoskeleton.

Timeline and Cost

Activities	FY 16	17	18	19
Text (12 participants enrolled)	Completed			
Text (30 participants to be enrolled)				
Text (48 participants to be enrolled)				
Text (64 participants to be enrolled)				
Estimated Budget ($K)	**$352**	**$371**	**$381**	**$263**

Updated: (October 11, 2016)

Goals/Milestones

FY16 Goals – Startup, kick-off and training meetings at each site; Initiate participant enrollment

☑ Q3-Participant screening and enrollment of 4 participants/site.

FY17 Goal – Continued participant screening and enrollment

❑ Q2-Participant screening, recruitment and enrollment of 8 (JJPVAMC), 4 (KF) and 6 (UMROI) participants per respective sites.

FY18 Goal – Continued enrollment

☐ Q1-Participant enrollment of 8 (JJPVAMC), 4 (KF) & 6 (UMROI)

☐ Q4-Participant enrollment of 8 (JJPVAMC), 4 (KF) & 4 (UMROI)

FY19 Goal – Completion of data collection

☐ Q2-Completion of participants

☐ Q3 to Q4 -Completion of data edits, analysis; Manuscript preparation

Comments/Challenges/Issues/Concerns - None

Budget Expenditure to Date

Projected Expenditure FY16 (Year 1): Approximate $352,335

Actual Expenditure FY16 (Year 1): Approximate $352,335

9. APPENDICES: Nothing to Report